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**Patent and Trademark Office**

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08/380,051 01/30/95 MUKHERJEE

18N2/1124

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R	
EXAMINER	
ULM, J	
ART UNIT	PAPER NUMBER
	6

1812

DATE MAILED: 11/24/95

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.  | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152.       |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____   |

**Part II SUMMARY OF ACTION**

1. ☒ Claims 1 to 13 are pending in the application.  
Of the above, claims 4, 5, 10 to 13 are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 1 to 3, 6 & 9 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

**EXAMINER'S ACTION**

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1) Claims 12 to 29 are pending in the instant application. Claims 1 to 11 have been canceled and claims 14 to 29 have been added as requested by Applicant in Paper Number 8, filed 25 March of 1996.

2) Claims 12 and 13 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement (M.P.E.P. § 818.03(a)).

3) The numbering of claims is not accordance with 37 C.F.R. § 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 C.F.R. § 1.121(b), they must be renumbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 12 to 27 in Paper Number 8 have been renumbered 14 to 29, respectively.

4) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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5) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --  
(f) he did not himself invent the subject matter sought to be patented.

6) Claims 14 to 21 are rejected under 35 U.S.C. § 102(f) because the applicant did not invent the claimed subject matter. These claims are drawn to a chemical compound which was made by Clonetech Laboratories Inc. and purchased by Applicant, as indicated in lines 9 to 25 on page 51 of the instant specification. These claims encompass a cDNA comprising the nucleotide sequence of SEQ ID NO:1 of the instant specification as that cDNA occurs in any capacity and such a cDNA was present in the cDNA library that was purchased by Applicant from Clonetech Laboratories Inc. as evidenced by the fact that the claimed compound was isolated from this library. The nucleic acid of claim 18 was present in any human heart cDNA expression libraries such as the  $\lambda$ gt11 expression libraries that were old and well known in the art at the time of the instant invention.

7) Claims 22 to 29 are rejected under 35 U.S.C. § 103 as being unpatentable over the Chen et al. publication (BIOCHEM. BIOPHYS. RES. COMM 196(2):671-677, 29 Oct. 1993) in view of the

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Sher et al. publication (Biochem. 32:5598-5604, 1993) for those reasons of record in Paper Number 6.

Applicant has pointed out that neither of the cited references described the existence of a human PPAR $\gamma$  gene. This is correct. However, the information presented in this combination of references provided an artisan with a reasonable expectation that such a gene existed, that the protein product of that gene as well as the gene itself would be structurally and functionally analogous to the murine PPAR $\gamma$  gene and gene product described by Chen et al. as evidenced by the demonstrated similarity between the murine and human PPAR gene products of Sher et al. That artisan also had more than a reasonable expectation that a cDNA encoding the human PPAR $\gamma$  gene product could be isolated by screening a human heart cDNA library with the cDNA encoding the murine PPAR $\gamma$  since the murine PPAR $\gamma$  cDNA was isolated from a murine heart cDNA library. In the absence of unexpected results, a valid rejection under 35 U.S.C. § 103 only requires that an artisan of ordinary skill have the motivation and means to make the claimed invention and a reasonable expectation that a routine practice of the art will produced the expected invention. All of these elements are present in the instant rejection.

Applicant is advised that human PPAR $\gamma$  is a protein which is a chemical compound. Further, a cDNA encoding human PPAR $\gamma$  is

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also a chemical compound. The claimed invention is a composition containing that cDNA and not the cDNA itself. The nucleotide sequence of that cDNA is an innate property of that cDNA and the amino acid sequence of the human PPAR $\gamma$  protein encoded thereby is an innate property of that protein. Applicant did not invent either of these compounds. Applicant has made no inventive contribution which has altered the innate properties of either of these compounds. Therefore, Applicant's arguments regarding the novelty of the sequence of the DNA contained in the claimed composition is immaterial since this is an innate property of a preexisting compound and not the result of an inventive contribution by Applicant and the further characterization of an existing chemical compound does constitute an act of invention.

Applicant's position that an obviousness enquiry should focus "exclusively" on the product itself is without basis in law. It is clear that a rejection of a composition is flawed if it does not establish that the making of the claimed composition, as well as the composition itself, was in the hands of an artisan save for the routine practice of the art. The prior art did not have to suggest the specific changes that one would have to make in the cDNA of Chen et al. to arrive at the cDNA contained in the claimed composition since this was not an inventive step. As stated above, Applicant did not invent the cDNA contained in the claimed composition, they isolated it from other related

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compounds and, therefore, the instant rejection is based upon the fact that an artisan would have been motivated to take this inventive step, i.e. to isolate that cDNA complete with all of its innate properties, based upon the art of record.

Applicant's position that one could not have conceived of an isolated cDNA encoding human PPAR $\gamma$  based upon the description in Chen et al. of an analogous composition containing a cDNA encoding murine PPAR $\gamma$  unless one could have envisioned all of the innate properties of that cDNA such as its nucleotide sequence is in error. It is a matter of historical fact that a cDNA encoding a particular protein can be isolated and used without ever knowing the nucleotide sequence of that DNA. The fact that the amino acid sequence of the human PPAR $\gamma$  which is encoded by the cDNA contained in the composition of the instant invention is not identical to that of the murine PPAR $\gamma$  of Chen et al. is not surprising since this property usually varies between homologous proteins from different species. Whereas the innate properties of the human and murine PPAR $\gamma$  are not identical, the differences are neither unexpected or particularly relevant to the patentability of compositions containing those compounds. In Re Dillon, 16 USPQ2d 1897, held that "[p]rima facie case of obviousness of chemical composition is established if there is structural similarity between claimed and prior art subject matter, provided by combination of references or otherwise, and

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if prior art gives reason or motivation to make claimed composition". This decision further held that the "discovery that claimed composition possesses property not disclosed for prior art does not alone defeat prima facie case". The simple fact that the nucleotide sequence of the DNA encoding the murine PPAR $\gamma$  is different from the DNA sequence of the cDNA contained in the composition of the instant invention does not defeat the instant rejection since the prior art of record provided a composition containing a structurally similar compound and the motivation to make the claimed composition.

Arguments based upon the decision in *In re Deuel* are not applicable to the instant rejection because that decision did not address the obviousness of a first chemical composition in view of a prior art composition containing a structurally analogous compound. Additionally, the instant rejection is silent on "general" methods of "cloning". The instant rejection provides a very specific method of isolating a cDNA encoding a human PPAR by screening a human cDNA library with a cDNA encoding a murine PPAR as described on page 5599 of the Sher et al. publication. Therefore, the instant rejection is not in conflict with the decision in *In re Deuel*.

Applicant's arguments filed 25 March of 1996 have been fully considered but they are not deemed to be persuasive.

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Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm at telephone number (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, G. D. Draper can be reached on (703) 308-4232. The fax phone number for this group is (708) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800